510(k) Summary

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Device:	
Trade Name:	**DSM Biomedical PRP Device**
Common/Usual Name:	Platelet and Plasma Separator For Bone Graft Handling
Classification Name:	Automated Blood Separator
Classification Regulation:	21 CFR 864.9245
Device Class:	Class 2
Device Code:	ORG
Advisory Panel:	Hematology
Predicate Device:	BK070026: GPS III Mini Platelet Concentrate Separation Kit with ACD-A

Device Description:

The DSM Biomedical PRP Device is a compact point-of-care device which permits for the rapid preparation of autologous PRP from a small volume of a patient's blood. The PRP is separated from whole blood by means of a 30mL single-use disposable (processing unit) that is driven by a reusable centrifuge (base unit). The processing unit kit includes the processing unit, disposable accessories to aid in blood handling, and a vial of ACD-A to prevent coagulation of whole blood and PRP product during processing.

Intended Use:

The DSM Biomedical PRP Device is designed to be used for the safe and rapid preparation of autologous platelet-rich-plasma (PRP) from a small sample of blood at the patient's point of care. The PRP is mixed with autograft and/or allograft bone prior to application to a bony defect for improving handling characteristics.

Biocompatibility and Performance Data:

Biocompatibility testing, bench testing, electrical safety, electromagnetic compatibility, and PRP quality testing have been performed to evaluate the safety and effectiveness of the DSM Biomedical PRP Device.

Biocompatibility testing on patient contacting materials was completed on the finished sterile device and in accordance with the requirements of *ISO 10993-1: 2009, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process*. Results show that the device biocompatibility profile is acceptable.

Bench testing has been completed on the Base Unit and Processing Unit based on several international standards and internal test protocols. The test results verify that the DSM Biomedical PRP device is safe and effective.

Electrical safety testing has been completed in accordance with *ANSI/AAMI ES60601-1:2005 and C1:2009 and A2:2010 (IEC 60601-1:2005, MOD.) (Third Edition): Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*.

Electromagnetic compatibility testing has been conducted to verify compliance with the requirements of *ANSI/AAMI ES 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.*

PRP quality testing was performed based upon FDA recommendations for required testing. The quality of PRP produced by the DSM Biomedical PRP Device was shown to be non-inferior to the quality of PRP produced by the predicate device as shown in a side by side comparison study.

Substantial Equivalence:

Performance testing has confirmed that the DSM Biomedical PRP Device is substantially equivalent to the predicate device with regard to materials, intended use, operation, function, and technological characteristics, pursuant to section 510(k).